

INITIAL REVIEW ENGINEERING REPORT  
PMN: 18-0007 0008

Post-Focus Revision 3 12/10/2018  
ENGINEER: Al-Haddad \ LMK / MLS / JAS  
PV (kg/yr): [REDACTED]

Revision Notes / Assessment Overview: 6/20/18 Revision: Submitter provided updated information stating that no dust is expected to form from PVC containing PMN because [REDACTED]. No further supporting information was provided. The following changes were made to this IRER: (1) For USE, the inhalation exposures and dust releases were removed. // The CC was also revised from 1 ppb to 1000 ppb.

SUBMITTER: Nexoleum USA Corp

USE: Plasticizer and stabilizer for flexible polyvinyl chloride (PVC) plastic. [REDACTED]

[REDACTED] Consolidated Set P-18-07-08. Analogs [REDACTED] are for the same uses in PVC. P2REC: CRSS: forward. P2 Claims: The substance will be biodegradable, be a replacement for phthalate ester plasticizers, and have lower mammalian toxicity compared to the former.

OTHER USES: Analog [REDACTED]: plasticizer for water-based coatings;  
Analog [REDACTED]: polyol for use in polyurethane resin blends.

MSDS: Yes

Label: No

Gen Eqpt: Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment. Minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Wash thoroughly after handling. Use good industrial practice to avoid eye contact

Respirator: Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Health Effects: The product, in the form supplied, is not anticipated to produce significant adverse human health effects.

TLV/PEL:

CRSS :

Chemical Name: Glycerides, soya mono- and di-, epoxidized, acetates

S-H20: 0.00081 g/L @

VP: 1.0E-6 torr @

MW: 471.00 %<500 %<1000

Physical State and Misc CRSS Info:

Neat: Liquid Mfg: Solution: [REDACTED]

[REDACTED] Proc/Form: Solid blend:  
16.7% PMN substance entrained in PVC plastic End Use: Solid blend: PMN  
substance entrained in PVC plastic. The structures as drawn are  
representative. The submitter states that the substance is [REDACTED]

[REDACTED] The MW, MF and EPI estimations above are for the typical

[REDACTED]. Submitted Data:

Liquid. A 1H NMR spectrum is provided for the mixture with [REDACTED]

[REDACTED]. The MSDS is for  
the same mixture. Cont'd on p.6.

Consumer Use: No

SAT (concerns) (10/13/2017):

Related Cases and Misc SAT Info:

Analog: [REDACTED]

Migration to groundwater: Moderate

PBT rating: P3B1T1

Health: 1-2 Dermal, Drinking Water, Inhalation

Eco: 3 Water (All releases to water with a CC = 1000 ppb)

#### OCCUPATIONAL EXPOSURE RATING: [REDACTED]

#### NOTES & KEY ASSUMPTIONS:

Occupational exposure and environmental releases were estimated using the 9/30/2013 version of ChemSTEER tool. Input to ChemSTEER tool includes information from: the PMN submission, physical / chemical properties, relevant past cases, the 2004 GS for Additives in Plastics Processing (Converting into Finished Products), and the 2004 GS for Additives in Plastics Processing (Compounding). This IRER is a consolidated set P18-0007-0008. The PMN will initially be imported, but eventually it will be manufactured in the US. This IRER assesses manufacture, processing and use. // SAT concerns are for dermal, drinking water, or inhalation exposures. There are also concerns for water releases (cc = 1000 ppb). Migration to groundwater is moderate. // The following different-submitter, similar-use past cases were referenced for consistency: [REDACTED] None of the past cases assessed manufacturing; they all assessed converting and compounding. // MFG: This IRER assesses releases to incineration or landfill from equipment cleaning. This IRER also assesses dermal exposures during loading of liquid into transport containers. // PROC (compounding): This IRER assesses releases to air, water, incineration, and landfill from fugitive air and equipment cleaning. This IRER also assesses dermal exposures from unloading totes (consistent with past cases and GS). // USE (converting): This IRER assesses releases to air, water, incineration, and landfill consistent with the GS and past cases. This IRER also assesses dermal and inhalation exposures from cleaning container residue from compounding transport container (consistent with GS; inhalation consistent with past cases [REDACTED]).

#### POLLUTION PREVENTION CONSIDERATIONS:

P2 Claims: Production of Nexo plasticizers will be from a biobased starting material: Soybean oil. In the future other vegetable oils may also be used, depending on the price of alternate oils. Nexo plasticizers are cost competitive with and will be replacements for petroleum-based plasticizers such as phthalates. Nexo plasticizers build upon well-known and widely used epoxidized soybean oil (ESO). ESO is an excellent PVC stabilizer, but is not an effective primary plasticizer for many PVC applications. The Nexo product is both a stabilizer and plasticizer and competes well with traditional products, including phthalate-based PVC plasticizers. Nexo plasticizers can completely replace phthalate-based PVC plasticizers in most applications. The Nexo plasticizers are produced from soybean oil or other vegetable oils, rather than petroleum-based feedstocks. These materials are safer to the environment due to the increased biodegradability of products and raw materials. They also have lower mammalian toxicity compared to the still-dominant phthalate plasticizers, such as di-2-ethylhexyl phthalate (DEHP), diisononyl phthalate (DINP), and diisooctyl phthalate (DIOP). The product will initially be imported, but Nexoleum anticipates transferring production to the U.S. to take advantage of the abundant and inexpensive soybean oil and other sources of vegetable oils. P2REC: CRSS: forward.

EXPOSURE-BASED REVIEW: [REDACTED] ([REDACTED])

- 1) # of workers exposed: [REDACTED] >1000? [REDACTED]
- 2) >100 workers with >10 mg/day inhalation exposure: [REDACTED]
- 3) (a) >100 workers w/1-10 mg/day inh. exp. & >100 days/yr: [REDACTED]  
(b) Routine Dermal Cont: >250 workers & >100 days/yr: [REDACTED]

INITIAL REVIEW ENGINEERING REPORT

PMN: 18-0007 0008

MFG: Plasticizer

Number of Sites/ Location: 20

unknown site(s)

Days/yr: 240

Basis: The submission estimates [REDACTED], [REDACTED] kg product/batch, and 240 exposure days per year. CS calculates 20 sites and [REDACTED] kg PMN/batch.

Process Description:

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

(per submission)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Incineration or Landfill

Conservative: [REDACTED] kg/site-day over 240 days/yr from 20 sites  
or [REDACTED] kg/site-yr from 20 sites or [REDACTED] kg/yr-all sites  
to: Incineration or Landfill

from: Equipment Cleaning Losses of Liquids from Multiple Vessels  
basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. The submission states that water is not involved in the production of the PMN or for equipment cleanup. It also states that no routine cleanup is performed on the production equipment or storage tank. RAD assesses equipment cleaning using the standard model to incineration or landfill as conservative.

RELEASE TOTAL

[REDACTED] kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 60

Basis: The submission estimates 3 workers potentially exposed per site. RAD assumes that all workers perform all activities and that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

negligible (VP < 0.001 torr); No mist generation is expected during manufacture.

Dermal:

Exposure to [REDACTED] at [REDACTED] concentration

High End:

> Potential Dose Rate: [REDACTED] mg/day over 240 days/yr

> Lifetime Average Daily Dose: [REDACTED] mg/day over 240 days/yr

> Average Daily Dose: [REDACTED] mg/day over 240 days/yr

> Acute Potential Dose: [REDACTED] mg/day over 240 days/yr

Number of workers (all sites) with dermal exposure: 60

Basis: Loading Liquid Product into Rail Cars; EPA/OPPT 2-Hand Dermal Contact with Liquids Model. Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

INITIAL REVIEW ENGINEERING REPORT

PMN: 18-0007 0008

PROC: PVC Compounding

Number of Sites/ Location: 1

unknown site(s)

Days/yr: 250

Basis: The submission estimates [REDACTED] and 16.7% PMN in the product. RAD assumes 250 operating days per the 2004 Plastics Compounding GS and [REDACTED] kg PMN Input/site.batch ([REDACTED] kg PMN / 250 days). CS calculates 1 site.

Process Description:

[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED] (per submission and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.



Water

Output 2: [REDACTED] kg/site-day over 250 days/yr from 1 site  
or [REDACTED] kg/site-yr from 1 site or [REDACTED] kg/yr-all sites  
to: Air (50%) and Water (50%)

from: Fugitive Air from Compounding

basis: User-Defined Loss Rate Model. The submission did not provide an estimate for this release. The GS states that while the PMN is non-volatile, mixing operation may be performed at elevated temperatures; thus slight volatilization may occur. The GS estimates a conservative LF of 0.05%. Particles are originally released to air but subsequent condensation may result in losses to water. As a conservative estimate 50% is assume to be released to water and 50% is assumed to be released to the atmosphere.

Air

Output 2: [REDACTED] kg/site-day over 250 days/yr from 1 site  
or [REDACTED] kg/site-yr from 1 site or [REDACTED] kg/yr-all sites  
to: Air (50%) and Water (50%)

from: Fugitive Air from Compounding

basis: User-Defined Loss Rate Model. The submission did not provide an estimate for this release. The GS states that while the PMN is non-volatile, mixing operation may be performed at elevated temperatures; thus slight volatilization may occur. The GS estimates a conservative LF of 0.05%. Particles are originally released to air but subsequent condensation may result in losses to water. As a conservative estimate 50% is assume to be released to water and 50% is assumed to be released to the atmosphere.

Incineration or Landfill

Conservative: [REDACTED] kg/site-day over 250 days/yr from 1 site  
or [REDACTED] kg/site-yr from 1 site or [REDACTED] kg/yr-all sites  
to: Incineration or landfill (per submission)

from: Residual from Compounding Equipment Cleaning

basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. The submission does not provide release estimates, but states that water is not used to clean the containers ro clean spills.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

RAD assesses this release to incineration or landfill as conservative.

RELEASE TOTAL

[REDACTED] kg/yr - all sites

#### OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 24

Basis: The GS estimates 24 workers exposed per site (25,557 workers in industry / 715 sites x 66% production workers). RAD assumes that all workers perform all activities and that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

negligible (VP < 0.001 torr); Mists and dust generation are not expected during PVC compounding.

Dermal:

Exposure to [REDACTED] at [REDACTED] concentration

High End:

> Potential Dose Rate: [REDACTED] mg/day over 250 days/yr

> Lifetime Average Daily Dose: [REDACTED] mg/day over 250 days/yr

> Average Daily Dose: [REDACTED] mg/day over 250 days/yr

> Acute Potential Dose: [REDACTED] mg/day over 250 days/yr

Number of workers (all sites) with dermal exposure: 24

Basis: Unloading Liquid Raw Material from Totes; EPA/OPPT 2-Hand Dermal Contact with Liquids Model. Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

INITIAL REVIEW ENGINEERING REPORT

PMN: 18-0007 0008

USE: Converting PVC into products

Number of Sites/ Location: 11

unknown site(s)

Days/yr: 250

Basis: Submission provides PV of [REDACTED] kg/yr and 16.7% in PV formulation. No other information provided. Per the 2004 Plastics Converting GS, the daily use rate of additive = [REDACTED] kg PMN/site day. Therefore, number of sites = [REDACTED] = 10.93 sites. EPA assumes 11 sites. CS calculates [REDACTED] kg PMN/day.

Process Description:

[REDACTED] (per GS and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. Submitter provided updated information stating that [REDACTED] Therefore, RAD does not assess potential container releases from dust formation.

#### Water

Output 2: █████ kg/site-day over 250 days/yr from 11 sites  
or █████ kg/site-yr from 11 sites or █████ kg/yr-all sites  
to: Water (50%) or air (50%) (per model)  
from: Fugitive Air from Converting Activities  
basis: User-Defined Loss Rate Model. The ESD estimates that 0.25% of the daily use rate may be released because of slight volatilization during converting operations at elevated temperatures. Particles are originally released to air, but about 50% is assumed to be condensed and released to water.

#### Water or Incineration or Landfill

Output 2: █████ kg/site-day over 250 days/yr from 11 sites  
or █████ kg/site-yr from 11 sites or █████ kg/yr-all sites  
to: Water, incineration, or landfill (per model)  
from: Equipment Cleaning Losses of Solids from Process Vessels  
basis: User-Defined Loss Rate Model. The ESD estimates that 2% is released to water from equipment cleaning. This includes cooline water used during converting and equipment cleaning water.

#### Air

Output 2: █████ kg/site-day over 250 days/yr from 11 sites  
or █████ kg/site-yr from 11 sites or █████ kg/yr-all sites  
to: Water (50%) or air (50%) (per model)  
from: Fugitive Air from Converting Activities  
basis: User-Defined Loss Rate Model. The ESD estimates that 0.25% of the daily use rate may be released because of slight volatilization during converting operations at elevated temperatures. Particles are originally released to air, but about 50% is assumed to be condensed and released to water.

#### RELEASE TOTAL

█████ kg/yr - all sites

#### OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 0

Basis: The GS estimates 48 workers exposed per site (736,698 total workers / 12,191 total sites x 79% production workers). RAD assumes that all workers perform all activities and that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

Submitter provided updated information stating that [REDACTED]

[REDACTED]  
Therefore, RAD does not assess potential inhalation exposures from dust formation.

Dermal:

Non-Quantifiable (Some surface contact may occur if manually transferred) - in cast solids (such as molded plastics) or in matrices such as extruded pellets.